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| APPLICATION NO.                     | FILING DATE                       | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.    | CONFIRMATION NO. |
|-------------------------------------|-----------------------------------|----------------------|------------------------|------------------|
| 10/084,592                          | 02/25/2002                        | Ronald L. Cravens    | 56510.10002            | 5751             |
|                                     | 7590 12/05/200<br>KWELL SANDERS L |                      | EXAMINER               |                  |
| 4801 Main Street                    |                                   |                      | OGUNBIYI, OLUWATOSIN A |                  |
| Suite 1000<br>KANSAS CITY, MO 64112 |                                   |                      | ART UNIT               | PAPER NUMBER     |
|                                     |                                   |                      | 1645                   |                  |
|                                     |                                   |                      |                        |                  |
|                                     |                                   |                      | MAIL DATE              | DELIVERY MODE    |
|                                     |                                   |                      | 12/05/2008             | PAPER            |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

|  | Application No.   | Applicant(s)  |  |  |  |
|--|---|---|--|--|--|
|  | 10/084,592  | CRAVENS, RONALD L.  |  |  |  |
| Office Action Summary  | Examiner  | Art Unit  |  |  |  |
|  | OLUWATOSIN OGUNBIYI   | 1645  |  |  |  |
| The MAILING DATE of this communication appearing for Reply   | ppears on the cover sheet with the o  | correspondence address  |  |  |  |
| A SHORTENED STATUTORY PERIOD FOR REP WHICHEVER IS LONGER, FROM THE MAILING  - Extensions of time may be available under the provisions of 37 CFR of after SIX (6) MONTHS from the mailing date of this communication.  - If NO period for reply is specified above, the maximum statutory perional Failure to reply within the set or extended period for reply will, by status Any reply received by the Office later than three months after the mail earned patent term adjustment. See 37 CFR 1.704(b).  | DATE OF THIS COMMUNICATION 1.136(a). In no event, however, may a reply be tild will apply and will expire SIX (6) MONTHS from the, cause the application to become ABANDONE | N. mely filed the mailing date of this communication. ED (35 U.S.C. § 133). |  |  |  |
| Status   |   |   |  |  |  |
| Responsive to communication(s) filed on 10     This action is FINAL. 2b)☑ The 3)☐ Since this application is in condition for allow closed in accordance with the practice under  | nis action is non-final.<br>vance except for formal matters, pro  |   |  |  |  |
| Disposition of Claims  |   |   |  |  |  |
| 4) Claim(s) 1-16 is/are pending in the application  4a) Of the above claim(s) 4,5,14 and 15 is/are  5) Claim(s) is/are allowed.  6) Claim(s) 1-3,6-13 and 16 is/are rejected.  7) Claim(s) 2-3 and 6-13 is/are objected to.  8) Claim(s) are subject to restriction and are subjected to by the Examination of the corresponding of the corresponding to the cor | e withdrawn from consideration.  /or election requirement.  ner. ccepted or b) □ objected to by the se drawing(s) be held in abeyance. Se                                   | e 37 CFR 1.85(a).   |  |  |  |
| 11) The oath or declaration is objected to by the I  | •   | •                                     |  |  |  |
| Priority under 35 U.S.C. § 119   |   |   |  |  |  |
| <ul> <li>12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).</li> <li>a) All b) Some * c) None of:</li> <li>1. Certified copies of the priority documents have been received.</li> <li>2. Certified copies of the priority documents have been received in Application No</li> <li>3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).</li> <li>* See the attached detailed Office action for a list of the certified copies not received.</li> </ul>  |   |   |  |  |  |
| Attachment(s)  1) Notice of References Cited (PTO-892)  2) Notice of Draftsperson's Patent Drawing Review (PTO-948)  3) Information Disclosure Statement(s) (PTO/SB/08)  Paper No(s)/Mail Date   | 4)  Interview Summary Paper No(s)/Mail D 5)  Notice of Informal F 6)  Other:  | ate   |  |  |  |

Claims 1-16 are pending in the application. Claims 1-3, 6-13 and 16 are under examination. Claims 4-5 and 14-15 are withdrawn as being drawn to non-elected invention or species.

Specification

The disclosure is objected to because of the following informalities:

The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. See p. 9. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

Appropriate correction is required.

Election/Restrictions

Applicant's election of the invention of Group I, claims 1-13 and the species bacteria in reply to the restriction requirement mailed 8/15/08 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 4-5 and 14-15 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention and species, there being no allowable generic or linking claim.

## Claim Objections

Claims 2-3 and 6-13 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

Claim 1 recites "a biologically active compound' however the dependent claims recite that the compound contains one or more agents or substances or components. The recitation of 'more biologically active agents', for example, broadens 'a biologically active compound' because in claim 1 there is only one compound i.e. 'a biologically active compound'.

#### Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2-3 and 6-13 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are drawn to a method for treating an animal to achieve a positive effect on the health of the animal comprising applying a biologically-active compound to the muzzle of an Application/Control Number: 10/084,592 Page 4

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animal which subsequently cleans its muzzle with its tongue, thereby distributing the compound into the oral and/or nasal cavities of the animal to contact the nasal and/or oral mucosa.

The instant specification does not define biologically active compound. The recitation that 'the compound contains one or more' is vague and therefore confusing. Does Applicant mean that a biologically active *composition* comprising one or more agents such as those listed in claims 6 and 7? Does Applicant mean for instance that a composition comprising a biological active compound wherein the composition further comprises alum or oil or sugars? How can alum or aluminum hydroxide or oil (see claim 11) or sugars, or carbohydrates or sucrose (see other compounds as in claim 12) or compounds that contains components that provide enhanced viscosity have a positive effect on the health of animal? Does Applicant mean for instance that a composition comprising a biological active compound wherein the composition further comprises alum or oil or sugars? Appropriate clarification of the claims is requested provided support exists for such in the specification

As to claim 10 the recitation of *components thereof* is vague and indefinite as the specific component being referred to is not clear and the specification does not define *components thereof* as used in the claim.

## Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 8 and 13 are rejected under 35 U.S.C. 102(b) as being anticipated by Vaillancourt et al US 4,402,941. Sept. 6, 1983.

The claims are drawn to a method for treating an animal to achieve a positive effect on the health of the animal comprising applying a biologically-active compound to the muzzle of an animal which subsequently cleans its muzzle with its tongue, thereby distributing the compound into the oral and/or nasal cavities of the animal to contact the nasal and/or oral mucosa.

Vaillancourt et al teaches a method for treating a feline or other animals to achieve a positive effect on the health of the animal comprising applying a biologically –active compound to the muzzle (impregnating muzzle with medicine) wherein the animal subsequently cleans itself and then ingests the medicine when it cleans itself by licking (with tongue), thus distributing the medicine into nasal or oral mucosa. See abstract and column 2 lines 40-45.

Vaillancourt et al teaches the compound is a pharmaceutical for preventing disease of the urinary system (column 1 lines 7-24, or pharmaceutical to treat bacteria (antibiotic). Vaillancourt et al teaches that the compound contains hormones (anovulant), inorganic medicants (vitamins, sodium chloride) or organic medicants (green plant powder) and contains additional component that provided enhanced viscosity (green plant powder) or adhesive characteristics (sawdust, wood shavings). See column 4 lines 24-35, column 4 lines 62 to column 5 lines 1-24 and claims 1-16.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-3, 6-9, 11, and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Merck Veterinary Manual 8<sup>th</sup> Edition 1998 (whole book, since the whole book cannot be scanned some exemplary pages are cited: 348-349, 358-361, 1644-1651, 1866-1869, 1972-1874) in view of Vaillancourt et al US 4,402,941. Sept. 6, 1983.

The claims are drawn to a method for treating an animal to achieve a positive effect on the health of the animal comprising applying a biologically-active compound to the muzzle of an animal which subsequently cleans its muzzle with its tongue, thereby distributing the compound into the oral and/or nasal cavities of the animal to contact the nasal and/or oral mucosa.

The Merck Veterinary Manual teaches many pharmaceuticals and vaccines for prevention and/or treatment of various diseases of the respiratory system, the reproductive system,

the urinary system, the gastrointestinal/digestive system, the integument/musculoskeletal system, the hemolymphatic system, the endocrine system, the nervous system, the eve and ear. See whole book. For example, the Manual teaches treatments antibiotics (tetracycline) for the treatment of Chlamydiosis a disease of the eye in felines (p. 359-361). The Manual also teaches biologically active compounds such as live, attenuated or killed or altered organisms (gene deleted) or subunits of microorganisms or immuno- modulating substances (such as antibodies) and adjuvants for co-administration with antigens to enhance an immune response (aluminum hydroxide, alum and immunostimulants which do not need to be administered with antigen such as Mycobacteria bovis live attenuated, Mycobacteria bovis cell wall, acemannon( polymannose, a polysaccharide), endotoxins etc (p. 1867-1874). The manual teaches pharmcotherapeutics for the gastrointestinal/digestive system, integumentary system, muscular system, reproductive system, nervous system, endocrine (hormonal therapy) and circulatory system (hemolymphatic system). See pages 1644-1651. The manual teaches that drugs can be administered orally via paste or liquid (p. 1650) or vaccines taken in orally via feed or drinking water (p. 1870 under administration of vaccines).

Vaillancourt et al teaches a method for treating a feline or other animals to achieve a positive effect on the health of the animal comprising applying a biologically –active compound to the muzzle (impregnating muzzle with medicine) wherein the animal subsequently cleans itself and then ingests the medicine when it cleans itself by licking (with tongue). Said method of licking the muzzle necessarily means distributing the medicine into nasal or oral mucosa. See abstract and column 2 lines 40-45. Vaillancourt teaches that said method of administration i.e.

applying to the muzzle can be used for administering any other preparation or compositions for preventing or treating other diseases (column 4 lines 25-33).

It would have been prima facie obvious to apply any of the biologically active compounds of The Merck Veterinary to the muzzle of a animal as Vaillancourt teaches that an animal in the process of cleaning itself licks the compound and ingests the compound into the oral mucosa. Said method of licking the muzzle will also distribute the compound into the nasal cavity and nasal mucosa. The motivation is provided by Vaillancourt who teaches that said method of administration i.e. applying to the muzzle can be used for administering any other preparation or compositions for preventing or treating other diseases (column 4 lines 25-33) thus avoiding difficulty in orally administering medicine to an animal (Vaillancourt column 2 lines 17-28). Furthermore, it is prima facie obvious that one of skill in the art would reasonable spread the liquids or pastes comprising the biologically active compound unto the muzzle of said animal when applying to the muzzle.

Claims 1-3, 6-7, 9, 12, 13 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chu et al US 2002/0025325 A1 filed June 21, 2001 in view of Vaillancourt et al US 4,402,941. Sept. 6, 1983

The claims are drawn to a method for treating an animal to achieve a positive effect on the health of the animal comprising applying a biologically-active compound to the muzzle of an animal which subsequently cleans its muzzle with its tongue, thereby distributing the compound into the oral and/or nasal cavities of the animal to contact the nasal and/or oral mucosa.

Chu et al teaches a biologically active composition comprising live, attenuated or killed biological organisms e.g. bacteria such as *Chlamydia psittaci* which causes Chlamydiosis disease of the eye, or *Mycoplasma hyponeumoniae* (respiratory disease) or rickettsia (*Ehrlichiosis canis* which causes hemolymphatic disease) and a palatable flavorant such as plant flavorings (strawberry) or sugars e.g. glucose or fructose syrups – syrups also provide enhanced viscosity (paragraphs 24, 29, 45, 46-52, 56 to 85).

Vaillancourt et al teaches a method for treating a feline or other animals to achieve a positive effect on the health of the animal comprising applying a biologically –active compound to the muzzle (impregnating muzzle with medicine) wherein the animal subsequently cleans itself and then ingests the medicine when it cleans itself by licking (with tongue), thus distributing the medicine into nasal or oral mucosa. See abstract and column 2 lines 40-45. Vaillancourt teaches that said method of administration i.e. applying to the muzzle can be used for administering any other preparation or compositions for preventing or treating other diseases (column 4 lines 25-33).

It would have been prima facie obvious to apply any of the biologically active compounds of Chu et al to the muzzle of an animal as Vaillancourt teaches that an animal in the process of cleaning itself licks the compound and ingests the compound into the oral mucosa. Said method of licking the muzzle will also distribute the compound into the nasal cavity and nasal mucosa. The motivation is provided by Vaillancourt who teaches that said method of administration i.e. applying to the muzzle can be used for administering any other preparation or compositions for preventing or treating other diseases (column 4 lines 25-33) thus avoiding difficulty in orally administering medicine to an animal (Vaillancourt column 2 lines 17-28).

Furthermore, it is prima facie obvious that one of skill in the art would reasonable spread the liquid comprising the biologically active compound unto the muzzle of said animal when applying to the muzzle.

Claims 1-3, 6-7, 9, 10 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Livingston et al US 4, 692,412, 1987 in view of Vaillancourt et al US 4,402,941. Sept. 6, 1983

The claims are drawn to a method for treating an animal to achieve a positive effect on the health of the animal comprising applying a biologically-active compound to the muzzle of an animal which subsequently cleans its muzzle with its tongue, thereby distributing the compound into the oral and/or nasal cavities of the animal to contact the nasal and/or oral mucosa.

Livingston et al teaches a biologically active compound comprising killed biological organisms e.g. bacteria such as *Progenitor cryptocides* which causes diseases of the integument system (connective tissue) or urinary system (kidney) for the treatment of animals and teaches oral administration (column 4 lines 39-56, column 14 lines 49-60, column 16 lines 47-64, column 22 lines 34-38, column 26 claim 1).

Livingston et al does not teach applying said biologically-active compound to the muzzle of an animal which subsequently cleans its muzzle with its tongue, thereby distributing the compound into the oral and/or nasal cavities of the animal to contact the nasal and/or oral mucosa

Vaillancourt et al teaches a method for treating a feline or other animals to achieve a positive effect on the health of the animal comprising applying a biologically –active compound

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to the muzzle (impregnating muzzle with medicine) wherein the animal subsequently cleans itself and then ingests the medicine when it cleans itself by licking (with tongue), thus distributing the medicine into nasal or oral mucosa. See abstract and column 2 lines 40-45. Vaillancourt teaches that said method of administration i.e. applying to the muzzle can be used for administering any other preparation or compositions for preventing or treating other diseases (column 4 lines 25-33).

It would have been prima facie obvious to apply the biologically active compound of Livingston et al to the muzzle of an animal as Vaillancourt teaches that an animal in the process of cleaning itself licks the compound and ingests the compound into the oral mucosa. Said method of licking the muzzle will also distribute the compound into the nasal cavity and nasal mucosa. The motivation is provided by Vaillancourt who teaches that said method of administration i.e. applying to the muzzle can be used for administering any other preparation or compositions for preventing or treating other diseases (column 4 lines 25-33) thus avoiding difficulty in orally administering medicine to an animal (Vaillancourt column 2 lines 17-28). Furthermore, it is prima facie obvious that one of skill in the art would reasonable spread the liquid comprising the biologically active compound unto the muzzle of said animal when applying to the muzzle.

### Status of the Claims

Claims 1-3, 6-13 and 16 are rejected. No claims allowed.

# Prior Art Made of Record Pertinent to Applicants Disclosure

8 in 1 Kittymalt Hairball Remedy Original Malt Flavor, 1999-2008 PetFoodDirect.com.

Retrieved online 11/26/08

(http://www.petfooddirect.com/store/product\_detail.asp?pf\_id=3137501&dept\_id=113&brand\_i d=153&Page=) teaches that the hairball remedy can be applied to cat's nose so that the cat cleans it off and ingest the product.

#### Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to OLUWATOSIN OGUNBIYI whose telephone number is 571-272-9939. The examiner can normally be reached on M-F 8:30 am- 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Mondesi can be reached on 571-272-0956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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/Oluwatosin Ogunbiyi/ Examiner, Art Unit 1645 /Robert B Mondesi/ Supervisory Patent Examiner, Art Unit 1645